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ALLERGAN, INC.
2525 DUPONT DRIVE, T2-7H
IRVINE, CA 92612-1599

EXAMINER	
BADIO, BARBARA P	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN SEFTON

Appeal 2007-0864
Application 10/820,298
Technology Center 1600

Decided:[1] June 26, 2009

Before TONI R. SCHEINER, DONALD E. ADAMS, and DEMETRA J. MILLS, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1-11, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

STATEMENT OF THE CASE

The claims are directed to a method for treating proliferative skin diseases (claims 1-5) and a method for treating psoriasis in a human subject (claims 6-11). Claim 1 is illustrative:

1. A method for treating proliferative skin diseases comprising the administration of an effective amount of tazarotene and an effective amount of a corticosteroid.

The Examiner relies on the following evidence:

Yamamoto	US 5,236,906	Aug. 17, 1993
Nagpal et al.	US 5,650,279	Jul. 22, 1997
Sequeira et al.	US 4,775,529	Oct. 4, 1998
Smith	US 5,874,074	Feb. 23, 1999

Appellant relies on the follow evidence:

H. Gollnick and A. Menter, Combination therapy with tazarotene plus a topical corticosteroid for the treatment of plaque psoriasis, 140(Suppl. 54) British Journal of Dermatology 15-23 (1999).

Beddingfield Declaration, executed February 2, 2005.

The rejections as presented by the Examiner are as follows:

1. Claims 1-11 stand rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Yamamoto and Nagpal.

2. Claims 1-11 stand rejected under 35 U.S.C § 103(a) as unpatentable over Smith or Sequeira in combination with Nagpal.

We affirm.

PRINCIPLES OF LAW

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992). On appeal to this Board, Appellant must show that the Examiner has not sustained the required burden. *See Ex parte Yamaguchi*, 88 USPQ2d 1606, 1608 and 1614 (BPAI 2008) (precedential); *Ex parte Fu*, 89 USPQ2d 1115, 1118 and 1123 (BPAI 2008) (precedential); *Ex parte Catan*, 83 USPQ2d 1569, 1570 and 1577 (BPAI 2007) (precedential); *Ex parte Smith*, 83 USPQ2d 1509, 1512-1514, 1519 (BPAI 2007) (precedential).

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that is was obvious under § 103.

Id. at 421. It is proper to "take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418. *See also id.* at 421 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."). "In determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill

in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

> "[W]hen a prima facie case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability." *In re Glaug,* 283 F.3d 1335, 1338 (Fed. Cir. 2002). Rebuttal evidence is "merely a showing of facts supporting the opposite conclusion." *In re Piasecki,* 745 F.2d 1468, 1472 (Fed. Cir. 1984). . . . When a patent applicant puts forth rebuttal evidence, the Board must consider that evidence. *See In re Soni,* 54 F.3d 746, 750 (Fed. Cir. 1995) (stating that "all evidence of nonobviousness must be considered when assessing patentability"); *In re Sernaker,* 702 F.2d 989, 996 (Fed. Cir. 1983) ("If, however, a patent applicant presents evidence relating to these secondary considerations, the board must always consider such evidence in connection with the determination of obviousness.").

In re Sullivan, 498 F.3d 1345, 1351 (Fed. Cir. 2007). "When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over." *In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976); *In re Hedges*, 783 F.2d 1038, 1039 (Fed. Cir. 1986) ("If a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed").

However, in order to establish unexpected results for a claimed invention, objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support. *In re Greenfield*, 571 F.2d 1185, 1189 (CCPA 1978); *In re Lindner*, 457 F.2d 506, 508 (CCPA 1972); *In re Tiffin*, 448 F.2d 791, 792 (CCPA 1971).

The combination of Yamamoto and Nagpal:

ISSUE

Are Appellant's unexpected results sufficient to overcome the Examiner's prima facie case of obviousness?

FINDINGS OF FACT

FF 1. The instant Application is a continuation of Application No. 09/367,712, which was involved in Appeal Nos: 2002-1369 and 2005-0938. Application No. 09/367,712 subsequently issued as U.S. Patent No. 6,974,807.

FF 2. Appellant does not dispute the Examiner's conclusion that it would have been prima facie obvious at the time the invention was made to combine tazarotene and corticosteroid to treat skin disease (Ans. 3-4).

FF 3. Instead, Appellant contends that his evidence of unexpected results overcomes the Examiner's prima facie case of obviousness (App. Br. 3-11).

FF 4. Appellant discloses that the invention includes the use of low-potency, mid-potency, or high-potency corticosteroid (*see, e.g.,* Spec. 3: 20-21).

FF 5. Appellant discloses that in treating patients with a combination of tazarotene and corticosteroid "[t]he most common adverse events resulting from the treatment were burning, pruritus and erythema; however there was a lower incidence of such adverse events in patients treated with tazarotene plus the medium- or high-potency corticosteroid" (Spec. 9: 26-29).

FF 6. Appellant discloses that "treating psoriasis in humans with a combination of tazarotene and a mid-potency or high-potency corticosteroid

is more effective than a combination of tazarotene and low-potency or placebo and results in a lower incidence of adverse events such as burning pruritis and erythema" (Spec. 10: 1-4).

FF 7. Beddingfield declares that based upon the evidence in the instant application and in Gollnick "there appears to be a general trend that combinations of tazarotene and corticosteroids increase efficacy in the treatment of psoriasis while reducing the adverse events as compared to tazarotene alone" (Beddingfield Dec. ¶ 3).

FF 8. In this regard, Beddingfield declares that "based upon the same evidence, there appears to be a trend of reduction in adverse events for the combination treatment of tazarotene and corticosteroid as the potency of the corticosteroid is increased" (Beddingfield Dec. ¶ 6).

FF 9. According to Appellant's Specification,

The overall incidence of adverse events that were possibly, probably or definitely treatment-related decreased with increased corticosteroid potency, falling from 42% in the taz/plac group, to 36%, 32% and 31% in the tazarotene/low-potency corticosteroid (taz/low), taz/med, and taz/high groups, respectively. (See Table II, below.)

Table II. Overall incidence of adverse events

	Patients (%)			
	Taz/plac	Taz/low	Taz/med	Taz/high
Pruritus	15	19	16	8
Erythema	12	7	6	6
Irritation	8	9	5	4
Burning	6	4	4	8

(Spec. 12: 8-25.)

FF 10. In proceedings on Appeal No. 2005-0938, in parent application 09/367,712, Appellant's Appeal Brief included a table that compiled the total adverse events for each combination of tazarotene from placebo through high-potency corticosteroid (*see* 09/367,712, March 29, 2004 App. Br. 6 and Decision on Appeal No. 2005-0938: 9). For clarity that table is reproduced below:

	Patients (%)			
	Taz/plac	Taz/low	Taz/med	Taz/high
Total Adverse Events	41	39	31	26

(*Id.*)

FF 11. Gollinick reports on "the benefits of using a mid- or high-potency corticosteroid in an *additive* combination regimen with tazarotene, compared with tazarotene plus placebo" (Gollinick 22: col. 1, ll. 44-47).

FF 12. Gollinick reports that "[t]he addition of a mid- or high-potency topical corticosteroid to tazarotene therapy offers a valuable means of optimizing the efficacy and tolerability of treatment for plaque psoriasis" (Gollinick 22: col. 2, ll. 47-50).

ANALYSIS

The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 1 is representative and is drawn to a method for treating proliferative skin diseases. The method of claim 1 comprises the administration of an effective amount of tazarotene and an effective amount of a corticosteroid. The corticosteroid set forth in claim 1 is open to include the use of low-potency, mid-potency, or high-

potency corticosteroid (FF 4). Accordingly, claim 1 reads on a method comprising the administration of tazarotene and low-potency corticosteroid. Accordingly, we limit our discussion to the combination of tazarotene and low-potency corticosteroid.

Appellant contends that there is "a general reduction of adverse events for the combination of tazarotene and a corticosteroid as compared to tazarotene alone" (App. Br. 4). In addition, Appellant contends that while "the adverse event contribution of each of the drugs in a combination may be different, the total number of adverse events is the most important quantity to be evaluated in terms of unexpected results" (*id.*). In this regard, Appellant's contend that "the comparison of medium to high potency corticosteroid is irrelevant to whether combining corticosteroids with tazarotene results in reduced side effects as compared to tazarotene alone" (App. Br. 5).

We agree that the question is whether the combination of tazarotene with a low-potency corticosteroid results in reduced side effects relative to the use of tazarotene alone. Accordingly, we are not persuaded by Appellant's table illustrating the average of "the adverse event profile of the corticosteroid combination groups", e.g., the average of the observed side effects associated with tazarotene in combination with low-, mid-, *and* high-potency corticosteroid (App. Br. 6). This data tells us nothing about the reduction in side effects associated with the combination of tazarotene and a low-potency corticosteroid.

The total number of adverse events for tazarotene alone or in combination with low-, mid-, or high-potency corticosteroid as reported by Appellant in Table II (FF 9) is reproduced below:

	Patients (%)			
	Taz/plac	Taz/low	Taz/med	Taz/high
Total Adverse Events	41	39	31	26

(FF 10.) Appellant's Reply Brief recognizes, however, that there is a discrepancy between the data recorded in Table II of Appellant's Specification and the text that corresponds to Table II. Specifically, while the total adverse events from Table II is accurately reproduced in the foregoing table, Appellant's Specification reports that the total "incidence of adverse events is 42% for tazarotene alone, and 36%, 32%, and 31% for the tazarotene/low-, med-, and high-potency corticosteroid respectively" (Reply Br. 7). While Appellant recognizes the discrepancy – Appellant contends that "both sets of data points [come] to the same conclusion. The groups receiving both tazarotene and a corticosteroid had fewer adverse events than those that received tazarotene only" (*id.*). We are not persuaded.

Instead, we consider the data presented in Table II (FF 9) to be most relevant as this is the data that was used and represented on Appeal in an effort to demonstrate an "unexpected" result (FF 10). We are, however, not persuaded that the data presented in Table II of Appellant's Specification establishes unexpected results for a method of treating skin disease comprising administering a combination of tazarotene and a low-potency corticosteroid. In this regard, we recognize the complete lack of any statistical analysis establishing that the four percent difference (*see, e.g.,* FF

10) in adverse effects between the treatment with tazarotene alone (e.g., Taz/plac) and tazarotene in combination with a low-potency corticosteroid is relevant and unexpected. To the contrary, it would appear that at the time the Specification was written Appellant agreed that "treating psoriasis in humans with a combination of tazarotene and a mid-potency or high-potency corticosteroid is more effective than a combination of tazarotene and *low-potency* or placebo and results in a lower incidence of adverse events such as burning pruritis and erythema" (FF 6 (emphasis added)).

We recognize Appellant's reliance on the post-filing date Gollinick reference (*see, e.g.,* App. Br. 7). We also recognize Appellant's tables and graphs of the numbers reported in Gollinick and conclusion that Gollinick supports the full breath of the invention set forth in claim 1 (*see generally,* App. Br. 7-9 and Reply Br. 9-12). We are not persuaded.

While Gollinick does experiment with low-potency corticosteroid, Appellant does not identify and we do not find a teaching in Gollinick that suggests the use of a low-potency corticosteroid for the treatment of any disease. Instead, Gollinick limits its discussion to mid- and high-potency corticosteroids (FF 11-12). The Beddingfield Dec., which relies on Appellant's Specification and Gollinick, fairs no better at making a specific fact based statement that suggests that a method of treating a skin disorder with a combination of tazarotene and low-potency corticosteroid would be expected to exhibit a reduction in adverse effects over the use of tazarotene alone.

Therefore, despite Appellant's contention that two experts have observed the trend asserted by Applicant (App. Brief, 8), neither Beddingfield nor Gollinick state that the combination of tazarotene and low-

potency corticosteroid results in a reduction of adverse effects. Stated differently, while there may be a "trend" associated with increased corticosteroid potency, the question is when does this "trend" become statistically relevant? There is no evidence on this record that the reported results for tazarotene in combination with placebo is statistically different than the results reported for tazarotene in combination with low-potency corticosteroid.

In order to establish unexpected results for a claimed invention, objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support. *In re Greenfield*, 571 F.2d at 1189. For the foregoing reasons, the evidence on this record fails to establish unexpected results for a combination of tazarotene and low-potency corticosteroid. Accordingly, the evidence of record is not commensurate in scope with claim 1.

CONCLUSION OF LAW

Appellant's unexpected results are not sufficient to overcome the Examiner's prima facie case of obviousness.

The rejection of claim 1 under 35 U.S.C § 103(a) as unpatentable over the combination of Yamamoto and Nagpal is affirmed. Since they are not separately argued, claims 2-11 fall together with claim 1.

Smith or Sequeira in combination with Nagpal:

ISSUE

Are Appellant's unexpected results sufficient to overcome the Examiner's prima facie case of obviousness?

FINDINGS OF FACT

FF 13. Appellant does not dispute the Examiner conclusion that it would have been prima facie obvious at the time the invention was made to combine tazarotene and corticosteroid to treat skin disease (Ans. 5).

ANALYSIS

Appellant contends that "[t]he arguments made for part A 'Rejection over Yamamoto and Nagpal above also apply here" (App. Br. 11).

For the reasons set forth above, we are not persuaded.

CONCLUSION OF LAW

Appellant's unexpected results are not sufficient to overcome the Examiner's prima facie case of obviousness.

The rejection of claim 1 under 35 U.S.C § 103(a) as unpatentable over Smith or Sequeira in combination with Nagpal is reversed. Since they are not separately argued claims 2-11 fall together with claim 1.

AFFIRMED

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

dm

ALLERGAN, INC.
2525 DUPONT DRIVE, T2-7H
IRVINE, CA 92612-1599